

Remarks

Prior to entry of this amendment, claims 1-28 were pending in the application and were subject to a three-way restriction. By this amendment, claims 1, 3, and 19 have been amended; the amendment to claim 1 is discussed in detail below. Claims 3 and 19 are amended to improve their readability. None of these amendments introduce new matter. After entry of this amendment, **claims 1-28 are pending.**

Applicants expressly reserve the right to pursue protection for any subject matter removed from consideration by this amendment.

Restriction Requirement

It is alleged that there are three inventions encompassed by the current claims, and that they do not form a single inventive concept under the PCT rules in view of Duarte *et al.* (1994). The claims have been assigned to the following groups:

Group I	Claims 1-8, 12-13, 17, and 22-23, drawn to an isolated recombinant polypeptide comprising amino acid segments from HIV-1 proteins, compositions thereof; <Species Election required, between protein sequences in claim 17>
Group II	Claims 9-11, 18-21, and 27-28, drawn to an isolated nucleic acid encoding the recombinant polypeptide, a vector comprising the nucleic acid, a host cell transformed with the vector, and a composition comprising the nucleic acid; <Species Election required, between nucleic acid sequences in claim 19>
Group III	Claims 14-16 and 24-26, drawn to methods of inhibiting or treating HIV and methods of enhancing an immune response in a subject.

The requirement to restrict the claims is made because the Duarte *et al.* reference is alleged to disclose a “multi-epitope polypeptide” that is equivalent to the “technical feature” of Applicants’ claims as it is defined in the Office action. Applicants traverse the requirement for restriction, at least because the special technical feature of Applicants’ invention has not been properly characterized by the Office, and the cited reference is not in fact relevant to actual special technical feature(s) of Applicants’ invention. Applicants request that the restriction be withdrawn or modified in view of the amendments and arguments made herein.

It is clear from the subject application that a special technical feature of the current invention is that the polypeptide comprises epitopes from or conserved across a plurality of HIV-1 subtypes (or clades). This is clear in the title (which refers to “multi-clade” constructs), the summary (*e.g.*, at page 5, lines 9, 13-14, and 17-18), and throughout the Specification (*e.g.*, at page 17, lines 17-35; page 18, line 34 through page 19, line 15; and page 21, line 19) including specifically the Examples (*e.g.*, page 27, lines 30-38; page 28, lines 3-18 and Table 1 [related to CTL epitopes]; and, page 37, lines 10-11 and Table 7 [related to B-cell epitopes] and Table 8 [related to T-helper epitopes]). Applicants have amended claim 1 herewith to explicitly indicate that the polypeptide comprises “epitopes selected to be at least 50% sequence conserved across a plurality of HIV-1 subtypes”.

This special technical feature is an explicit or inherent requirement of each and every one of the pending claims. It is recited specifically in claim 1, and is inherent in the features of the specific sequences in claim 17 (see teachings of the Specification, *e.g.*, at page 27, line 36 [referring to the “conserved B, T-helper and CTL epitopes” selected by Applicants]; page 28, lines 15-16 [which indicates that the selected epitopes “were great than 50% conserved” and “the majority of the epitopes were >90% conserved for [HIV] subtypes A/B/C/D/E/F/G”]; similar criteria were used to select B-cell (Table 7) and T-helper (Table 8) epitopes). Further, all of the nucleic acid claims and method claims depend (directly or indirectly) from a polypeptide claim that requires this special technical feature. Thus, it is a requirement of each and every one of the pending claims that the polypeptide comprises epitopes from a plurality of HIV-1 subtypes.

Moreover, this special technical feature defines a contribution over the prior art for all of the claimed subject matter (whether it is viewed as a single invention or a group of inventions). There is no reference of record in the case that reads on a polypeptide comprising epitopes from a plurality of HIV-1 epitopes, or which comprises “epitopes selected to be at least 50% sequence conserved across a plurality of HIV-1 subtypes” as currently claimed. Duarte *et al.* teach at best a multi-epitope polypeptide where each of the four epitopes is from HIV of a single subtype (that is, subtype B). Nothing in the teachings of Duarte *et al.* indicates that they

considered or in any way recognized any potential benefit of using epitopes that are sequence conserved (at any level) across multiple HIV subtypes. Thus, Duarte *et al.* is not relevant to the special technical feature discussed above, and Applicants claims (which include that special technical feature) define a specific, unique, and significant contribution over the art.

Since unity of invention exists among all of the Groups in the present application, it is inappropriate to subject the claims to restriction. Applicants request that the requirement be withdrawn, that all of Groups I through III be rejoined, and that all of the claims be examined in the current case.

Species Election Requirement

Applicants are being required also to elect a single species (sequence) of polypeptide (for Group I) or nucleic acid (for Group II), from those listed in claim 17 or 19 respectively. Separate from the arguments above, Applicants request rejoiner of at least some of the alleged separate species into sets based on their shared characteristics. These various shared characteristics are discussed in the Specification in detail, including in the short description of the Sequence Listing that begins on page 7.

For instance, SEQ ID NOs: 2, 4, 5 and 6 (and corresponding nucleic acids SEQ ID NOs: 1 and 3) all comprise CTL epitopes. Further, SEQ ID NOs: 2 and 4 differ with regard to whether or not ubiquitin is included, as do SEQ ID NOs: 5 and 6. Sequences of additional CTL antigenic fragments/epitopes are provided in SEQ ID NOs 11-22.

Similarly, SEQ ID NOs: 8 and 10 (and corresponding nucleic acid SEQ ID NOs: 7 and 9) all comprise B-cell and T-helper epitopes, with or without LIMP-II sequences. Sequences of additional B-cell (SEQ ID NOs: 46-59) and T-helper cell (SEQ ID NOs: 60-64) antigenic fragments/epitopes are also provided.

Applicants request that the various sequence “species” be considered within the context of these similarities, either at the outset or at least when species are being recombined upon the allowance of generic claims.

Election

Under protest, and only to comply with 37 CFR §1.499, Applicants hereby provisionally elect Examiner's Group I (defined in the Office action as corresponding to claims 1-8, 12, 13, 17 and 22-23).

Applicants further elect SEQ ID NO: 4 as the polypeptide sequence species on which examination will be initially carried out. Applicants understand that additional species will be recombined in the current case when a generic claim (e.g., claim 1 or 17) is found to be allowable. It is noted that the specific sequences enumerated in claim 17 are within the scope of claim 1.

In accord with 37 CFR §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement/species election reconsidered, if it is maintained in spite of this response.

Request for Rejoinder of Method Claims

Applicants have elected claims to a product/composition (polypeptides, and nucleic acids if they are recombined); process claims are included in the case that depend from or otherwise include all the limitations of elected claims. These process claims are currently assigned to Examiner's Group III, which different from the Group(s) to which the composition(s) is assigned (I and II). Applicants expressly request that the process claims be rejoined and the claims examined, at the latest upon the allowance of any of the composition claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for restriction practice in TC1600.

Conclusion

Applicants request complete withdrawal, or modification, of the requirement for restriction between the claims in view of the amendments and arguments made above. Examiner Kinsey is invited to telephone the undersigned if any questions remain concerning the

requirement for restriction, or this response. Otherwise, the present application is ready for substantive examination, and such action is requested.

Respectfully submitted,

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